The Global Language of Business

UDI in Europe

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The new EU Medical Device Regulations: Introduction to the future EU UDI System and to its implementation

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Device identification system: a UDI system is established

Scope:

- Apply to **all medical devices placed on the market except custom-made devices**

Approach:

- Substantially based on internationally recognised principles and guidance

Use of UDI:

- Basic UDI-DI is the access key for device-related information entered in EUDAMED
- Reference to Basic UDI-DI in key documentation (Declaration of conformity, certificates)
- UDI shall be used for reporting serious incidents and field safety corrective actions
- UDI storage obligations for Class III implantable devices

UDI issuing entities

- The European Commission shall designate **by means of implementing acts** UDI issuing entities provided that they satisfy certain criteria.

- Such criteria include:

- the entity system for the assignment of UDIs is adequate to identify a device through its distribution and use in accordance with the requirements of the Regulation;
- the entity system for the assignment of UDIs conforms to the relevant international standards;
- the entity gives access to its system for the assignment of UDIs to all interested users according to a set of predetermined and transparent terms and conditions.

- Until the Commission has designated UDI issuing entities, **GS1, HIBCC, ICCBBA** shall be considered as designated issuing entities.

Assignment/Submission of UDI data/UDI carrier

- Before placing a device on the market, the manufacturer shall **assign** to the device and – if applicable – to all higher levels of packaging a UDI.

- The **UDI carrier** shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.

- Before a device is placed on the market the manufacturer shall ensure that the **information** referred to in Part B of Annex V of the device in question is correctly **submitted and transferred** to the UDI database

- In some cases, the manufacturer is required to assign a Basic UDI-DI to the device before applying for the conformity assessment (the Notified Body will include a reference to the BASIC UDI-DI in the certificate).

Main deadlines

- **UDI assignment and submission of UDI core data elements to the database**: date of application of the new Regulations (unless EUDAMED is not functional by that date).

- **Placement of the UDI carrier**:

- Implantable devices and Class III devices (and Class D IVDs): 1 year after the date of application.
- Class IIa and Class IIb devices (Class C and B IVDs): 3 years after the date of application;
- Class I devices (Class A IVDs): 5 years after the date of application;
- Reusable devices that shall bear the UDI Carrier on the device itself: 2 years after the date applicable for its respective class of devices.

Additional important aspects

- The notion of **BASIC UDI-DI**
- Legal responsibilities of **manufacturers, importers, distributors** in relation to UDI
- UDI data elements: the **medical device nomenclature** in the EU UDI Database
- UDI-PI components: **manufacturing date** to be included only if it is the only production identifier which appears on the label
- New UDI-DI is required under certain foreseen conditions
- In case of space constraints on the label, **AIDC** format to be favoured unless devices are intended to be used outside health institutions (**HRI**)
- Direct marking on the device for **reusable devices**, with some exemptions
- **No ad-hoc exemptions are foreseen**
- Specific rules for implantable devices, systems and procedure packs, configurable devices, device software

FOCUS 1: Main features of Basic UDI-DI

- It is independent/separate from the packaging/labelling of the device
- It does not appear on any trade item
- It is different from the “Unit of Use DI” notion (as the Unit of Use DI identifies the last possible level of identification of a trade item used in the supply chain).
- It has to be globally unique
- It is the main key in the database and relevant certificates to identify a device with same attributes and essential characteristics

FOCUS 2: Legal conditions that future medical device nomenclature shall fulfil

Four main conditions

- ✓ is available free of charge to manufacturers and other natural or legal persons required by this Regulation to use that nomenclature
- ✓ is available to other stakeholders free of charge, where reasonably practicable
- ✓ is internationally recognised
- ✓ its code must be accessible to the public

Implementation of the UDI system (1/2)

- *Priorities:*
  - Implementing acts to designate issuing entities
  - Other guidance to provide detailed technical specifications for smooth implementation - Priority list of issues for guidance: Basic UDI-DI (including examples and specific cases); Definition of UDI data elements; Format of UDI data elements (EUDAMED); When new Basic UDI-DI is required
  - Medical device nomenclature to be made available

Implementation of the UDI system (2/2)

- *Governance (pending developments related to establishment of the MDCG):*
  - DG GROW in charge of implementing the UDI system
  - EU Expert Group on UDI to help preparing regulatory acts/guidance related to UDI implementation and to provide a platform for continuous exchange with stakeholders – close cooperation with the EUDAMED UDI WG
  - The UDI Expert Group has nominated two task-forces to deal respectively with guidance on UDI and nomenclature, with the latter being composed of MS experts only

Thank you for your attention